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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,229	02/11/2002	Bernd Sundermann	148/50899	1645

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EXAMINER

SAEED, KAMAL A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/071,229	SUNDERMANN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kamal A Saeed	1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 8-21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2,4,7 and 22 is/are rejected.
- 7) ☒ Claim(s) 3,5 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: _____                                    |

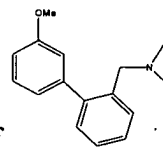
### DETAILED ACTION

Claims 1-23 are pending in this application. Claims 8-21 and 23 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference which anticipates one group would not render obvious the other.

Receipt is acknowledged of Information Disclosure Statement B, filed on November 12, 2001, which has been entered in the file.

### *Response to Restriction*

Applicant's election with partial traverse of Group I, claims 1-7 and 22, drawn to



compounds of formula I, as defined in claim 1, and the species of (3'-methoxybiphenyl-2-ylmethyl)dimethylamine and its corresponding hydrochloride salt, the species appearing first in claim 7, in paper No. 9 is acknowledged. The traversal is on the ground(s) that the method of use claim 23 is restricted away from the compound and composition claims i.e., claims 1-7 and 22. This is not found persuasive because in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims, process of making thereof and method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper. In the instant case, the compounds and compositions of claims 1-7, and 22 are not found allowable. Therefore, the restriction requirement in paper No. 7 is still deemed proper and is made FINAL.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the non-elected subject matter.

### *Status of the Claims*

Claims 1-7 and 22 are pending in this application. The generic concept of the elected subject matter is follows:

Compound of formula I, of claim 1, wherein

$R^1$ ,  $R^2$  and  $R^3$  independently represent, H, F, Cl, Br, CN, NO<sub>2</sub>, OR<sup>6</sup>, NR<sup>6</sup>R<sup>7</sup>, a C<sub>1-6</sub> alkyl, aryl, or an aryl group bonded via a C<sub>1-6</sub> alkylene group

$R^1$  and  $R^2$  together do not form any heterocyclic ring

$R^4$ ,  $R^5$ ,  $R^6$  and  $R^7$  are as defined.

As a result of the election and the corresponding generic concept identified, the remaining subject matter of claims 1-7 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 1-7 and 22 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

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***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7 and 22 are rejected under 35 U.S.C. 102(b) as being unpatentable as being anticipated by Montgomery et al. (US 4,473,709) or Wu et al (WO 9822433) or Misiorny et al., *Acta Pharm. Suec.* 14, pp 105-112, 1977.

Applicants claim substituted 2-dialkylaminoalkylbiphenyl compound or physiologically tolerated salt.

Montgomery et al teach, biphenyl-2-ylmethyldimethylamine hydrochloride which reads on species No. 15, of the compounds listed in claim 7 (See '709, claim 1).

Wu et al, teach biphenyl-2-methanamine which reads on formula I, wherein  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^5$ ,  $R^6$  and  $R^7$  each represent hydrogen and  $n$  is 1 (See CAS Abstract RN 1924-77-2, copy attached).

Misiorny et al teach, (2-methoxybiphenyl-2-yl-methyl)dimethylamine which reads on formula I, wherein  $R^1$  and  $R^2$  each represent H;  $R^3$  is methoxy group;  $R^4$  and  $R^5$  each represent a methyl group and  $n$  is 1 (See page 106, compound XVII).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 7 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al (US 4,473,709) or Wu et al (WO 9822433) or Misiorny et al., *Acta Pharm. Suec.* 14, pp 105-112, 1977.

Applicants claim substituted 2-dialkylaminoalkylbiphenyl derivatives and their pharmaceutical composition.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Montgomery et al teach, biphenyl-2-ylmethyldimethylamine hydrochloride and their use (See '709, claim 1).

Wu et al, teach biphenyl-2-methanamine compounds and their pharmaceutical use (See '709, claim 1).

Misiorny et al teach 2-dialkylaminoalkylbiphenyl derivatives (See page 106, compound XVII), their corresponding salts ( see page 109, the process of preparing compound VI ) and their pharmaceutical activity (See page 105)

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The biphenyl-2-ylmethyldimethylamine derivatives taught by Montgomery et al are homologs to the 2-dialkylaminoalkylbiphenyl derivatives of applicant's claims. One of the

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difference between the claimed 2-dialkylaminoalkylbiphenyl derivatives and that of the reference herein lie in that the phenyl group could be substituted by a methyl group in this application as opposed to H, of the prior art.

The biphenyl-2-methanamine derivatives taught by Wu et al are analogs to the 2-dialkylaminoalkylbiphenyl derivatives of applicant's claims. One of the difference between the claimed 2-dialkylaminoalkylbiphenyl derivatives and that of the reference herein lie in that the amine could be a secondary amine in the claims of this application as opposed to primary amine of the reference. The 2-dialkylaminoalkylbiphenyl derivatives taught by Misiorny et al are analogs to the 2-dialkylaminoalkylbiphenyl derivatives of applicant's claims. One of the difference between the claimed 2-dialkylaminoalkylbiphenyl derivatives and that of the reference herein lie in that the methoxy group is attached at **position 3** of the phenyl ring in this application as opposed to **position 2** of the reference.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

One skilled in the art would expect that the instant claims which are homologs/analog to Montgomery et al, prima facie. It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make claimed 2-dialkylaminoalkylbiphenyl derivatives with methyl substituent in the phenyl ring derives from the expectation that structurally similar compounds generally expected to have similar properties and have similar utilities.

One skilled in the art would expect that the instant claims which are homologs/analog to Wu et al, prima facie. It is well established that the substitution of methyl for hydrogen on a

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known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make claimed 2-dialkylaminoalkylbiphenyl derivatives with methyl substituent in the N derives from the expectation that structurally similar compounds generally expected to have similar properties and have similar utilities.

Misiorny et al are analogous art because Misiorny et al compounds possess similar activity. One skilled in the art would expect that the instant claims which are positional isomers to Misiorny et al, prima facie. Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Misiorny et al, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950). The motivation to make claimed 2-dialkylaminoalkylbiphenyl derivatives with substituent at different position of the phenyl ring arises from the expectation that structurally compounds are generally expected to have similar properties and have similar utilities.

### ***Claim Objections***

Claims 1, 7 and 22 are objected to for containing non-elected subject matter. Claims drawn solely to the elected invention as identified supra, would appear allowable. The claims must be amended to exclude non-elected subject matter.

Claims 3, 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



*Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

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Kamal Saeed, Ph.D.  
December 12, 2002



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Art Unit 1626, Group 1620  
Technology Center 1